EXHIBIT A

CIVIL ACTION COVER SHEET | DOCKET NO. 04-1771 B | **Trial Court of Massachusetts Superior Court Department** County: _____

PLAINTIFF(S)	DEFENDANT(S)
Mary Mullany	Wyeth, Inc; Wyeth Pharm. Inc. Intern
ATTORNEY, FIRM NAME, ADDRESS AND TELEPHONE Michael Hugo Lopez Hodes Restaino Milman & Skikos 95 Commercial Wharf Boston 02110 Board of Bar Overseers number: 243890	ATTORNEY (if known)

Origin code and track designation

Place an x in one box only:

- [x] 1. F01 Original Complaint
- [ ] 2. F02 Removal to Sup.Ct. C.231,s.104 (Before trial) (F)
- [ ] 3. F03 Retransfer to Sup.Ct. C.231,s.102C (X)
- [ ] 4. F04 District Court Appeal c.231, s. 97 &104 (Aft trial) (X)
- [ ] 5. F05 Reactivated after rescript; relief from judgment/Order (Mass.R.Civ.P. 60) (X)
- [ ] 6. E10 Summary Process Appeal (X)

TYPE OF ACTION AND TRACK DESIGNATION (See reverse side)

CODE NO.	TYPE OF ACTION (specify)	TRACK	IS THIS A JURY CASE?
B05	Products Liab	(A)	(X) Yes ( ) No

The following is a full, itemized and detailed statement of the facts on which plaintiff relies to determi money damages. For this form, disregard double or treble damage claims; indicate single damages o

TORT CLAIMS

(Attach additional sheets as necessary)

A.	Documented medical expenses to date:	
1.	Total hospital expenses	$ 100,00
2.	Total Doctor expenses	$ 200,0
3.	Total chiropractic expenses	$
4.	Total physical therapy expenses	$
5.	Total other expenses (describe)	$
	Subtotal	$ 300,0
B.	Documented lost wages and compensation to date	$ 250,0
C.	Documented property damages to date	$
D.	Reasonably anticipated future medical and hospital expenses	$ 1 Millia
E.	Reasonably anticipated lost wages	
F.	Other documented items of damages (describe)	$
G.	Brief description of plaintiff's injury, including nature and extent of injury (describe)	

Permanent total disability from ingestion of Redux

$

TOTAL $ 1,550,0

FILED IN THE OFFICE OF THE CLERK OF THE COURTS FOR THE COUNTY OF ESSEX APR 26 2004 CLERK

CONTRACT CLAIMS

(Attach additional sheets as necessary)

Provide a detailed description of claim(s):

TOTAL $. .....

PLEASE IDENTIFY, BY CASE NUMBER, NAME AND COUNTY, ANY RELATED ACTION PENDING IN THE SUPERIOR COURT DEPARTMENT

"I hereby certify that I have complied with the requirements of Rule 5 of the Supreme Judicial Court Uniform Ru Dispute Resolution (SJC Rule 1:18) requiring that I provide my clients with information about court-connected d resolution services and discuss with them the advantages and disadvantages of the various methods."

Signature of Attorney of Record _____ DATE: 4/2

AOTC-6 mtc005-11/99
A.O.S.C. 1-2000

CIVIL ACTION COVER SHEET INSTRUCTIONS

SELECT CATEGORY THAT BEST DESCRIBES YOUR CASE

	CONTRACT			REAL PROPERTY			MISCELLANEOUS	
A01	Services, labor and materials	(F)	C01	Land taking (eminent domain)	(F)	E02	Appeal from administrative Agency G.L. c. 30A	
A02	Goods sold and delivered	(F)	C02	Zoning Appeal, G.L. c.40A	(F)			
A03	Commercial Paper	(F)	C03	Dispute concerning title	(F)	E03	Action against Commonwealth Municipality, G.L. c.258	
A08	Sale or lease of real estate	(F)	C04	Foreclosure of mortgage	(X)			
A12	Construction Dispute	(A)	C05	Condominium lien and charges	(X)	E05	All Arbitration	
A99	Other (Specify)	(F)	C99	Other (Specify)	(F)	E07	c.112,s.12S (Mary Moe)	
	TORT					E08	Appointment of Receiver	
				EQUITABLE REMEDIES		E09	General contractor bond, G.L. c.149,s.29,29a	
B03	Motor Vehicle negligence-personal injury/property damage	(F)	D01	Specific performance of contract	(A)			
B04	Other negligence-personal injury/property damage	(F)	D02	Reach and Apply	(F)	E11	Workman's Compensation	
			D06	Contribution or Indemnification	(F)	E14	Chapter 123A Petition-SDP	
B05	Products Liability	(A)	D07	Imposition of Trust	(A)	E15	Abuse Petition, G.L.c.209A	
B06	Malpractice-medical	(A)	D08	Minority Stockholder's Suit	(A)	E16	Auto Surcharge Appeal	
B07	Malpractice-other(Specify)	(A)	D10	Accounting	(A)	E17	Civil Rights Act, G.L.c.12,s.11H	
B08	Wrongful death,G.L.c.229,s2A	(A)	D12	Dissolution of Partnership	(F)	E18	Foreign Discovery proceeding	
B15	Defamation (Libel-Slander)	(A)	D13	Declaratory Judgment G.L.c.231A	(A)	E96	Prisoner Cases	
B19	Asbestos	(A)	D99	Other (Specify)	(F)	E97	Prisoner Habeas Corpus	
B20	Personal Injury-Slip&Fall	(F)				E99	Other (Specify)	
B21	Environmental	(A)						
B22	Employment Discrimination	(F)						
B99	Other (Specify)	(F)						

TRANSFER YOUR SELECTION TO THE FACE SHEET.

EXAMPLE:

CODE NO.	TYPE OF ACTION (SPECIFY)	TRACK	IS THIS A JURY CASE?
B03	Motor Vehicle Negligence-Personal Injury	(F)	☒ Yes ☐ No

SUPERIOR COURT RULE 29

DUTY OF THE PLAINTIFF. The plaintiff or his/her counsel shall set forth, on the face sheet (or attach additional sheets as necessary), a statement specifying in full and itemized detail the facts upon which the plaintiff then relies as constituting mc damages. A copy of such civil action cover sheet, including the statement as to the damages, shall be served on the defen together with the complaint. If a statement of money damages, where appropriate is not filed, the Clerk-Magistrate shall tra the action as provided in Rule 29(5)(C).

DUTY OF THE DEFENDANT. Should the defendant believe the statement of damages filed by the plaintiff in any respect inadequate, he or his counsel may file with the answer a statement specifying in reasonable detail the potential damages w may result should the plaintiff prevail. Such statement, if any, shall be served with the answer.

A CIVIL ACTION COVER SHEET MUST BE FILED WITH EACH COMPLAINT, BUFF COLOR PAPER.

FAILURE TO COMPLETE THIS COVER SHEET THOROUGHLY AND ACCURATELY MAY RESULT IN DISMISSAL OF THIS ACTION.

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, SS

SUPERIOR COURT
TRIAL DIVISION
CIVIL ACTION
NO.: 04-1771

MARY MULLANY,

Plaintiff,

vs.

WYETH, INC.; WYETH PHARMACEUTICALS, INC.; WYETH-AYERST INTERNATIONAL, INC.; and INTERNEURON PHARMACEUTICALS, INC.

Defendants.

FILED
IN THE OFFICE OF THE
CLERK OF THE COURTS
FOR THE COUNTY OF MIDDLESEX
APR 26 2004
CLERK

04/26/04 16:23#0000 6417 CLERK

CIVIL	240.00
SURCHARGE	15.00
SECC	20.00
SUMMONS	20.00
041771 #	
SUBTTL	295.00
TOTAL	295.00
CHECK	295.00

COMPLAINT + JURY CLAIM

Plaintiff, by and through her undersigned counsel, alleges as follows:

INTRODUCTION

1. This case involves the diet drug dexfenfluramine, which was manufactured, sold, distributed and promoted by Defendants to capitalize on the public's obsession with being thin. Defendants misrepresented that dexfenfluramine was a safe and effective way to lose weight, when in fact the drug causes serious medical problems such as primary pulmonary hypertension and valve disease. The Food and Drug Administration has now taken dexfenfluramine off the market, but not soon enough to prevent Plaintiff from being injured.

2. This is an action for personal injuries and damages brought on behalf of the Plaintiff who has been prescribed and supplied with, received, and who has taken and ingested and consumed the diet drug, dexfenfluramine, as researched, designed, formulated, compounded,

tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages in order to enable the Plaintiff to treat the dangerous, severe and life-threatening side effects caused by this drug, including but not limited to cardiac valvular disease and disorders.

JURISDICTION AND VENUE

3. The injuries of Plaintiff were caused by the wrongful acts, omissions, and misrepresentations of Defendants.

4. Plaintiff is a resident of the Commonwealth of Massachusetts.

5. Personal jurisdiction exists in this venue because Defendants have done and continue to do substantial business in the Commonwealth of Massachusetts.

GENERAL ALLEGATIONS

6. At all times herein mentioned, "Defendants" or "Pharmaceutical Company Defendants" includes Wyeth, Inc., Wyeth Pharmaceuticals, Inc., Wyeth-Ayerst International, Inc., and Interneuron Pharmaceuticals, Inc., unless otherwise specified.

7. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their conduct constituted a breach of duty.

8. There exists, and at all times herein mentioned, there existed, a unity of interest in

ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as an entity distinct from other certain defendants will permit an abuse of the corporate privilege and would sanction fraud and would promote injustice.

9. At all times herein mentioned, the Pharmaceutical Company Defendants, and each of them were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the diet drug dexfenfluramine, hereafter "drug product".

10. At all times herein mentioned, the Pharmaceutical Company Defendants, and each of them, were authorized to do business within the Commonwealth of Massachusetts and did in fact supply the aforementioned products to consumers within the Commonwealth of Massachusetts .

11. At all times herein mentioned, the officers and directors of the Pharmaceutical Company Defendants named herein participated in, authorized and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the physical injuries described herein.

THE PARTIES

The Plaintiff

12. Plaintiff, Mary Mullaney, is a resident of the City of Melrose, Middlesex County, Massachusetts, who took the diet drug dexfenfluramine and was injured as a result.

13. Upon all information and belief, Ms. Mullaney took the drug for approximately 7 months. Her injuries as found by Dr. George Miller, include, but are not limited to moderate aortic regurgitation.

The Defendants

14. Defendant, Wyeth, Inc., is a corporation organized and existing under the laws of Delaware, with its principal place of business located in Pennsylvania. Said Defendant was in the business of manufacturing, marketing, distributing, and selling the drugs known as Pondimin and Redux, and it does substantial business in the Commonwealth of Massachusetts . Said Defendant may be served with process by delivering the Complaint and Summons to Wyeth, Inc., c/o Prentice Hall Corporation System, Inc., 2704 Commerce Drive, Harrisburg, Pennsylvania 17110.

15. Defendant, Wyeth Pharmaceuticals, Inc., is a corporation organized and existing under the laws of Delaware, with its principal place of business located in Pennsylvania. Said Defendant was in the business of manufacturing, marketing, distributing, and selling the drugs known as Pondimin and Redux, and it does substantial business in the Commonwealth of Massachusetts. Said Defendant may be served with process by delivering the Complaint and Summons to Wyeth Pharmaceuticals, Inc., c/o Prentice Hall Corporation System, Inc., 2704 Commerce Drive, Harrisburg, Pennsylvania 17110.

16. Defendant, Wyeth-Ayerst International, Inc., is a corporation organized and existing under the laws of New York, with its principal place of business located in Pennsylvania. Said Defendant was in the business of manufacturing, marketing, distributing, and selling the drugs known as Pondimin and Redux, and it does substantial business in the Commonwealth of Massachusetts. Said Defendant may be served with process by delivering the Complaint and Summons to Wyeth-Ayerst International, Inc., c/o Prentice Hall Corporation System, Inc., 2704 Commerce Drive, Harrisburg, Pennsylvania 17110.

17. Defendant Interneuron Pharmaceuticals, Inc., is a Corporation Chartered under the laws of the State of Delaware, having its principal place of business at 99 Hayden Ave, Lexington, Middlesex County, Commonwealth of Massachusetts. This defendant is a resident of the same county as the plaintiff.

FACTUAL ALLEGATIONS

Diet Drug Promotion

18. At all times relevant, Defendants, and each of them, themselves, or by and through the use of others, did manufacture, create, design, test, label, sterilize, distributed, supply, prescribe, market, sell, advertise, warn, and otherwise distribute in interstate commerce and in the Commonwealth of Massachusetts the pharmaceutical products known as fenfluramine and dexfenfluramine.

19. Pondimin and Redux are the trade names of the generic drugs fenfluramine and dexfenfluramine, respectively. Pondimin and Redux were utilized, prescribed, and sold by physicians for the management and treatment of obesity. Each of the drugs has been widely advertised and marketed by the named Defendants as safe and effective weight control

medications.

20. Fenfluramine (Pondimin) and dexfenfluramine (Redux) are sympathomimetic amines which have an anorectic, or diet suppressant, action mediated through the activation of serotonergic pathways in the brain. The serotonorgic pathways are those liberated, activated by, or involving serotonin in the transmission of nerve impulses.

21. Phentermine is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in treating obesity, the amphetamines. Its action, like that of the amphetamines, includes central nervous system stimulation and elevation of blood pressure. It has not been established that the action of this drug in treating obesity is primarily one of appetite suppression, and there may be other central nervous system actions and/or metabolic effects involved.

22. Phentermine, fenfluramine and dexfenfluramine are appetite suppressants that are chemically related and affect the level of serotonin in the brain. Serotonin is a chemical messenger that makes patients feel full after eating less food.

23. Each of these drugs, fenfluramine, phentermine and dexfenfluramine, has been widely advertised by the Defendants as effective weight control.

24. Fenfluramine and phentermine, when prescribed or ingested together, are popularly known, advertised, promoted and referred to as "fen/phen." The drugs were commonly prescribed in combination with each other and with dexfenfluramine. The fen/phen combination is also commonly prescribed in combination with dexfenfluramine.

25. Beginning in approximately 1995, prescription of the so-called "Fen/Phen" diet became extremely popular and, in 1996, the total number of prescriptions for phentermine and

fenfluramine in the United States alone exceeded 18 million. By contrast, in 1992, 1993 and 1994, before the "fen/phen" combination was popularized, sales were flat with only 50,000 prescriptions for fenfluramine written. In 1995 there were 1,000,000 fenfluramine prescriptions and 2,000,000 phentermine prescriptions written. Dexfenfluramine was approved for use in the United States in 1996 and there were approximately 2,000,000 prescriptions written for it even though it was only on the market 6 months.

26. On information and belief, Defendants, and each of them, have actively encouraged the combination use of these drugs which are the subject of this suit because Defendants knew that the combination use, though not approved by the FDA, would increase sales of each individual drug. The promotion of joint use of "fen/phen" significantly increased sales.

27. Defendants made filing(s) with the United States Food And Drug Administration ("FDA") in conjunction with the approval process for fenfluramine and dexfenfluramine, in the United States.

28. These drugs have been linked to several severe and life threatening medical disorders including, but not limited to, pulmonary hypertension, cardiac valvular disease and disorders, neurotoxicity, central and peripheral nervous system toxicity, neurocognitive dysfunction and developmental neurotoxicity.

29. Evidence linking the subject drug formulations to neurotoxicity and pulmonary hypertension has also been noted and reported in the medical literature since the mid-1970's. Researchers based at the National Institute of Mental Health reanalyzed animal data suggesting that fenfluramine and dexfenfluramine appeared to damage parts of brain cells at doses roughly

comparable to those prescribed to and consumed and ingested by Plaintiff. These known material risks were not disclosed to or shared with Plaintiff by any Defendant.

30. Defendants' strategy beginning in the early 1990's has been to aggressively market and sell these products by falsely misleading potential users about the products and by failing to protect users from serious dangers which Defendants knew or should have known to result from use of these products.

31. Defendants widely and successfully marketed phentermine, fenfluramine and dexfenfluramine in the United States, by undertaking an advertising blitz extolling the virtues of phentermine, fenfluramine and dexfenfluramine in order to induce widespread use of the products. The marketing campaign consisted of advertisements, promotional literature to be placed in the offices of doctors and other healthcare providers, and other promotional materials provided to potential Phentermine, fenfluramine and dexfenfluramine users.

32. The advertising program, as a whole, sought to create the image, impression and belief by consumers and physicians that the use of phentermine, fenfluramine and dexfenfluramine, both individually and in combination, was safe for human use, had fewer side effects and adverse reactions than other methods of weight loss, constituted a convenient, safe form of weight loss and would not interfere with daily life, even though the Defendants had no reasonable grounds to believe these representations to be true and in fact knew them to be false.

33. Defendants and each of them purposefully downplayed and understated the health hazards and risks associated with fenfluramine and dexfenfluramine. Defendants, through promotional literature, deceived potential users of phentermine, fenfluramine and dexfenfluramine by relaying positive information, including testimonials from satisfied users,

and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects. Defendants concealed material relevant information from potential fenfluramine and dexfenfluramine users and minimized user and prescriber concern regarding the safety of the phentermine, fenfluramine and dexfenfluramine.

34. In particular, in the materials produced by Defendants, Defendants falsely misrepresented the severity, frequency and nature of adverse health effects caused by phentermine, fenfluramine and dexfenfluramine, and falsely represented that adequate testing had been conducted concerning phentermine, fenfluramine and dexfenfluramine individually, and in combination.

35. As a result of the Defendants' advertising and marketing efforts, and representations concerning the subject products, the drugs are so pervasively prescribed throughout the United States that in excess of 18 million prescriptions for phentermine, fenfluramine and dexfenfluramine were written in the United States in the last full year these drugs were marketed.

36. Between 1994 and 1996, various Belgian doctors reported at least 30 cases of heart valve problems in diet pill users, and their reports were made to Belgian drug regulators as well as to Laboratoires Servier SA. Several Belgian doctors spoke with Servier officials and representatives by phone in 1994 to advise them of otherwise healthy patients who had taken fenfluramine, and who had various heart valve problems, including serious heart murmurs and valve leaks.

37. At all times relevant, Laboratoires Servier SA ("Servier") was engaged in the business of developing, testing and licensing for sale the diet drugs fenfluramine and

dexfenfluramine. Servier licensed dexfenfluramine and fenfluramine to American Home Products Corporation and/or Wyeth-Ayerst, and licensed dexfenfluramine to Interneuron Pharmaceuticals, Inc., for manufacture, distribution, sale and consumption in the United States and in the Commonwealth of Massachusetts, with the expectation that said diet drug products would be sold and purchased in the Commonwealth of Massachusetts. Servier licensed said diet drugs to said Defendants with the intention that the drugs would be sold and purchased in the Commonwealth of Massachusetts, in order to profit from the sale of said diet drugs in the Commonwealth of Massachusetts.

38. On information and belief, Plaintiff alleges that Defendants received actual notice from Servier of the Belgian medical reports. Furthermore, as responsible pharmaceutical manufacturers and distributors, Defendants had a duty to remain informed about the health risks associated with their products, and reasonably should have known of the widespread problems caused in Europe by the same drugs Defendants sold here in America.

PRIMARY PULMONARY HYPERTENSION

39. An August 26, 1996 article in The New England Journal of Medicine of the results of the International Primary Pulmonary Hypertension study ("IPPH Study") entitled "Appetite Suppressants and the Risk of Primary Pulmonary Hypertension" concluded that fenfluramine-based anorexigens, such as fen/phen, increased the risk of PPH by a multiple of more than 30 times. The Defendant Pharmaceutical Companies were aware of the results of the IPPH Study by at least November 1995, well in advance of its official publication in The New England Journal of Medicine in August 1996. Nevertheless, the Defendants failed to warn the public or physicians that the risk of contracting PPH was many, many multiples of that previously reported by the Defendant companies in their literature. Defendants have also failed to warn the public and physicians about the special risks of contracting PPH and other problems associated with the combination use of phentermine, fenfluramine and dexfenfluramine. The 1989 through 1997 editions of the Physician Desk Reference (PDR), which publishes warnings issued by drug manufacturers, mentioned only "four cases" of primary pulmonary hypertension (PPH), a disease with a 55% mortality rate, while in fact, the manufacturers were informed during the same period of over 100 cases of PPH during the same time period.

40. The International Primary Pulmonary Hypertension Study (IPPHS), published in1996, revealed that these drugs are a risk factor for the development of PPH, especially if they are used for more than three months, placing persons exposed to a risk factor of between 23 and 46 times higher than that expected in the general population. The 1997 PDR continued to represent that there were "four cases", despite internal manufacturer memos in 1995 and 1996 discussing the need to update the warning.

41. In addition to the failure to warn of known cases of PPH far in excess of the number mentioned in the PDRs, between 1989 and 1997, the manufacturers' agents were also warned of cases of valve damage associated with these drugs as early as 1990. In many instances, although required to do so by law, these Adverse Drug Effects or ADEs as they are known, were not reported to the FDA.

VALVULAR HEART DISEASE

42. In 1996, the Mayo Clinic noted a case of valvular heart disease following Fen-Phen therapy. In July of 1997, researchers at the Mayo Clinic in Rochester, Massachusetts, reported 24 cases of a rare valvular disease in women who took phentermine and fenfluramine in therapy combination. The Mayo Clinic report found a rare thickening of the heart valves. While normally the four valves of the heart close tightly to keep the blood flowing in one direction, the Mayo Clinic found that Fen-Phen appeared to injure the tissues of the heart valves so that the valves did not close completely and the blood leaked backward. The 24 patients had been using Fen-Phen for an average of one year and none of them had pre-existing heart disease when they began taking the drugs. Eight of the women had new documented pulmonary hypertension and five patients needed heart surgery to repair or replace damaged valves.

43. Between 1991 and 1996, the Defendants had received notice of reports of similar heart valve disease and complaints of heart valve regurgitation associated with use of the subject diet drugs, 31 of which met the FDA definition of valvulopathy. However, the defendants intentionally withheld most of this information from the FDA, which was only aware of 12 such problems between 1991 and 1996.

44. The Defendant Pharmaceutical Companies, and each of them, became aware and

had knowledge by as early as March 1996, of a striking and significant relationship between these drugs and defects of the valves of the heart. Researchers at the Mayo Clinic located in Rochester, Massachusetts, shared the findings of their study with the Defendants at that time. Nevertheless, the Defendants, and each of them, failed to inform the public, physicians, and patients that the risk of contracting primary pulmonary hypertension was many, many multiples of that previously reported by the Defendant companies, and each of them, in their written literature. Defendants, and each of them, also failed to warn the public, physicians, and patients prescribed and ingesting the drugs about the special and increased risks of contracting valvular heart disease through the combination use and increased risks of contracting valvular heart disease through the combination use of fenfluramine, dexfenfluramine and/or phentermine. Defendants, and each of them, also failed to inform Plaintiff and physicians of the reports in the literature of neurotoxicity and developmental neurotoxicity associated with use of the subject drugs, despite 80 published articles documenting neurotoxicity associated with dexfenfluramine alone, and similar findings associated with fenfluramine.

45. In March 1997, four months before the report was made public, Defendant Wyeth-Ayerst Division, a subsidiary of American Home, which was also the parent of Defendant Robins, obtained a detailed report from the Mayo doctors in a four hour meeting. At that time, there were five known cases of the heart valve problems. Later in March of 1997, Wyeth-Ayerst/American Home received information from doctors at MeritCare Medical Center in Fargo, North Dakota, about approximately 12 other cases of patients who developed heart valve problems after taking the diet drugs.

46. By August of 1997, there were at least 58 additional reports of valvular disease in

patients from at least 18 different states which were associated with the tandem use of phentermine and fenfluramine - including two male patients. The severity of the disease was graded as moderate or severe in three-fourths of the cases. The typical patient began showing heart symptoms after ten months of drug use. One 29-year-old woman died of a heart attack eight months after she first took the medicines. Six patients needed valve replacement surgery and more than ten needed surgery to repair the valves.

47. The valvupathy associated with these drugs is a fibrous sheath covering the surface of the heart valves, which limits the valve's ability to pump blood, causing a backflow of blood which reduces blood flow to vital organs and causes congestion of blood in the heart and lungs; the sheathing, or thickening, of the valves may also cause increasing damage, deterioration and eventual failure of the valves.

48. The form of valvular heart disease associated with Pondimin is serious, may require heart valve replacement surgery, and is potentially fatal. The widespread use of Pondimin by residents of Massachusetts, together with the high rate of occurrence of valvular heart disease among those who consumed Pondimin, have caused an imminent threat to public health and safety in the Commonwealth of Massachusetts.

49. In August of 1997, the Journal of the American Medical Association associated the use of Fen-Phen with brain dysfunction in animals. Researchers reviewing 128 medical journal articles concluded that Fen-Phen disrupted the brain functions in animals, and may cause depression, memory loss, anxiety and sleep disorders in humans as well as contributing to pulmonary hypertension in humans.

50. In August of 1997, the FDA asked Fen-Phen drug manufacturers to put "black

box"warnings on the labels of their medications and package inserts stressing these dangers. Defendants had not previously warned about valvular disease and had minimized or omitted the other risks and dangers. Defendants resisted revising their warnings.

51. In approximately September of 1997, the FDA received information from five physicians who had performed heart studies on patients who took Fen-Phen, dexFen-Phen or dexfenfluramine but who did not have symptoms of heart disease. Of the 291 asymptomatic patients screened, about 30% had abnormal valve findings, primary aortic regurgitation.

52. In September of 1997, manufacturers withdrew fenfluramine and dexfenfluramine from the market. The withdrawal was based on initial echocardiographic findings in five surveys indicating that approximately 30% of patients in these surveys who took the drugs had valvular abnormalities, even though most had no symptoms. This percentage is much higher than would be expected in the general population. The FDA warned against taking any of the remaining supplies. Phentermine remains on the market, but has been found to be less effective when taken alone.

53. On or about November 13, 1997, the U.S. Department of Health and Human services issued preliminary recommendations for the medical management of people who took the diet drugs fenfluramine or dexfenfluramine. Anyone who has taken fenfluramine or dexfenfluramine for any period of time, either alone or with another drug or drugs, should see a doctor for a medical history and physical examination to determine whether there are signs or symptoms of heart or lung disease. Anyone who has taken these drugs for any period of time, either alone or with another drug or drugs, who has signs or symptoms of heart or lung disease, such as a new heart murmur or shortness of breath, should have an echocardiogram performed.

An echocardiogram should be strongly considered for any patient who has taken these drugs, either alone or with another drug or drugs - regardless of whether the patient has signs and symptoms of the heart or lung diseases - BEFORE having any invasive procedure for which the American Heart Association recommends antibiotic prophylactic treatment to prevent the development of bacterial endocarditis. This will provide an accurate determination of whether antibiotic treatment is necessary.

54. Although the FDA had approved phentermine, fenfluramine and dexfenfluramine separately, the FDA has not approved these drugs for combination use. The manufacturers and distributors of these drugs knew of and encouraged the prevalence of off-label combination use of their drugs, and failed to warn physicians and consumers adequately and appropriately that the combination drug regimen was not FDA approved, was especially hazardous, was not recommended, and had not been systemically tested by appropriate clinical trials.

55. The product warnings about PPH in effect during the period when Plaintiff took the medications involved in this litigation were both substantively and graphically wholly inadequate to alert prescribing physicians and consumer patients about valve disease and the true pulmonary, cardiac and neurological risks associated with these drugs which was then known to the product and physician Defendants, and each of them.

56. The Pharmaceutical Company Defendants had actual knowledge, prior to fenfluramine and dexfenfluramine being taking off the market, that the drugs, either individually or in combination, increased the risks of PPH in multiples much greater than disclosed, and also caused valve disease. The manufacturers and distributors of phentermine, fenfluramine and dexfenfluramine, and each of them, did not adequately or appropriately disclose related drug

information to physicians in the United States. As a result, physicians have been over-prescribing phentermine, fenfluramine and dexfenfluramine to patients who have been grossly under informed regarding the risk of primary pulmonary hypertension, cardiac valve disease and neurotoxicity associated with the Defendants' diet pills.

57. Prior to the date on which the aforementioned products was ingested by Plaintiff, Defendants and each of them knew that these products were unsafe and had the potential and propensity to produce serious and/or life-threatening injuries and other damages. Notwithstanding the foregoing knowledge by the Defendants, at all times herein mentioned, Defendants failed to take appropriate action to cure the nature of said defects or to adequately warn users of said products and their physicians of said dangerous characteristics and defects.

58. At all times herein mentioned, Defendants have known that the subject drug products can cause serious and permanent physical injuries and they have failed to disseminate this information to or adequately warn governmental agencies, physicians, drug recipients and/or the general public, and have continued to advise physicians and the general public that the drugs do not cause any harm, thereby continuing their tortious activities against Plaintiff from the date of ingestion to the present.

59. Defendants, and each of them, have participated in the mutual exchange of information concerning the problems, dangers and health risks of the drugs and have provided information to each other designed to promote the sale of these drugs in general.

60. Plaintiff has sustained and will continue to sustain injuries on a continuing basis, by virtue of the drugs ingested, which have continued to cause injuries from the date of ingestion to the present.

61. The damages sustained by Plaintiff include but are not limited to general damages for pain and suffering, as well as loss of earnings and earning capacity and medical and other bills and expenses.

62. Plaintiff files this lawsuit pursuant to Section IV (D)(3) of the "Nationwide Class Action Settlement Agreement with American Home Products Corporation (as Amended)". Plaintiff is a Class Member who has been diagnosed by Qualified Physicians as FDA Positive by Echocardiograms performed between the commencement of Diet Drug use and the end of the Screening Period, and is eligible to exercise her right to Intermediate Opt-Out. Plaintiff timely submitted written notices of her intent to exercise her right to Intermediate Opt-Out by May 3, 2003. Plaintiff initiated her lawsuit against the Defendants within one year from the date on which her Intermediate Opt-Out right was exercised.

63. Plaintiff further pleads that any and all limitations statutes applicable to her cause of action alleged herein are tolled by the filing of various class actions.

64. At all times herein mentioned, Defendants, and each of them, (i) knew that the aforementioned products were dangerous and unsafe for ingestion in the human system as previously delineated in this Complaint; (ii) concealed said dangers and health risks from Plaintiff, physicians and the public in general; (iii) made misrepresentations to Plaintiff, physicians and the public in general as previously delineated in this Complaint; and (iv) with full knowledge of the health risks associated with the aforementioned products and without adequate warnings of same, manufactured, marketed and distributed said products for use by Plaintiff.

65. Prior to the manufacturing, sale and distribution of said drug products Defendants, and each of them, knew that said drug products were in a defective condition as previously

described, and knew that those who were prescribed and took the same would experience, and did experience, severe physical, mental and emotional injuries. Further, Defendants, and each of them, through their officers, directors and managing agents, had prior notice and knowledge from several sources, prior to the date of the dispensing of said drug products to Plaintiff, that the drugs presented a substantial and reasonable risk of harm to the public, including Plaintiff, and as such said consumers of said drugs were unreasonably subjected to risk of injury or death from the consumption of said drugs.

66. Despite such knowledge, Defendants, and each of them, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in said drugs and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in said drugs. Said Defendants and individuals intentionally proceeded with the manufacturing, sale and distribution and marketing of said drugs knowing persons would be exposed to serious potential danger, in order to advance their own pecuniary interests.

67. Defendants suppressed, concealed and misrepresented the true risks associated with these drugs in order to protect their profits and to capitalize on skyrocketing sales they knew to be associated with the "fen/phen" combination. As alleged above, sales of fenfluramine historically had been relatively flat, but several hundred percent as a result of the "fen/phen" combination. Defendants actively promoted the combination use, and deliberately concealed the risks, to protect and maximize the new revenues and to suppress adverse information that could have prevented the FDA's approval of dexfenfluramine, which was being sought by a related corporation.

FIRST CAUSE OF ACTION

(Strict Liability - Failure to Warn)

68. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

69. The drug products previously described were defective at the time of their manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution, in that, and not by way of limitation, said products and their warnings, instructions and directions failed to warn of the dangerous propensities of said products, which risks were known or reasonably scientifically knowable to Defendants. The Defendants, and each of them, knew or should have known of the defective condition, characteristics and risks associated with said products, as previously set forth herein.

70. At all times herein mentioned, the aforementioned products were defective, and Defendants, and each of them, knew that the products were to be used by the user without inspection for defects therein. Moreover, Plaintiff neither knew, nor had reason to know at the time of the use of the subject products, of the existence of the aforementioned defects.

71. As a result of the defective condition of the aforementioned products, Plaintiff suffered injuries and damages as alleged herein.

SECOND CAUSE OF ACTION

(Negligence)

72. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

73. At all times herein mentioned, Defendants, and each of them, had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe and adequately warn

of the risks and dangers of the aforementioned products.

74. At all times herein mentioned, Defendants, and each of them, negligently and carelessly manufactured, designed, formulated, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold the aforementioned products and failed to adequately test and warn of the risks and dangers of the aforementioned products.

75. As a result of said negligence and carelessness of the Defendants and each of them, Plaintiff suffered injuries and damages as alleged herein.

THIRD CAUSE OF ACTION

(Negligence Per Se)

76. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

77. At all times herein mentioned, Defendants, and each of them, had an obligation not to violate the law, in the manufacture, design, formulation, compounding, testing, production, processing, assembly, inspection, research, distribution, marketing, labeling, packaging, preparation for use, sale and warning of the risks and dangers of the aforementioned products.

78. At all times herein mentioned, Defendants, and each of them, violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301, et seq., related amendments and codes and federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law, and other applicable laws, statutes and regulations.

79. Plaintiff, as purchaser and consumer of the products, is within the class of persons the statutes and regulations described above are designed to protect, and Plaintiff's injuries are the type of harm these statutes are designed to prevent.

80. Defendants failed to meet the standard of care set by the following statutes and regulations, which were intended for the benefit of individuals such as the Plaintiff, making Defendants negligent per se. These violations include: (a) The labeling lacked adequate information on the use of the Fen-Phen combination, even though the Defendants were aware of the widespread use of the combination [21 C.F.R. Section 201.56(a) and (d)]; (b) The labeling lacked adequate information on the approximate kind, degree and duration of expected improvement for fenfluramine and dexfenfluramine alone or in combination with phentermine in violation of 21 C.F.R. Section 201.57(c)(3)(i); (c) The labeling did not state that there was a lack of evidence to support the common belief of the safety and advocacy of Fen-Phen. [21 C.F.R. 201.57(c)(3)(i) and (iv) and(c)(2)]; (d) The labeling failed to add warnings for pulmonary hypertension, serious heart conditions, and serious brain conditions as soon as there was reasonable evidence of their association with the drugs fenfluramine and dexfenfluramine, individually or in combination with phentermine [21 C.F.R. 201.57(e); (e) There was inadequate information for patients for the safe and effective use of the drugs fenfluramine and dexfenfluramine, individually or in concomitant use with phentermine in violation of C.F.R. 201.57(f)(2); (f) There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Defendants' drugs individually and Defendants' drugs in the Fen-Phen combination violation of 21 C.F.R. 201.57(f)(1); and (g) The labeling was misleading and promotional in violation of 21 C.F.R.201.56(b).

81. As a result of the violations of the statutes described above, Plaintiff suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION

(Breach of Implied Warranty)

82. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

83. Prior to the time that the aforementioned products were used by Plaintiff, Defendants, and each of them, impliedly warranted to Plaintiff and Plaintiff's agents and physicians that said products were of merchantable quality and safe and fit for the use for which they were intended.

84. Plaintiff was unskilled in the research, design and manufacture of the aforementioned products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using the aforementioned products.

85. The aforementioned products were neither safe for their intended use nor of merchantable quality, as warranted by Defendants, in that they had dangerous propensities when put to their intended use and would cause severe injuries to the user.

86. As a result of the aforementioned breach of implied warranties by the Defendants and each of them, Plaintiff suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION

(Breach of Express Warranty)

87. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

88. At all times herein mentioned, Defendants expressly warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned products were safe, effective, fit and proper for their intended use.

89. In utilizing the aforementioned products, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of the Defendants, and each of them. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.

90. As a result of the foregoing breach of express warranties by the Defendants, and each of them, Plaintiff suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION

(Negligent Misrepresentation)

91. Plaintiff incorporates the allegations of the foregoing paragraphs by reference.

92. Defendants, and each of them, from the time that the aforementioned products were first manufactured, marketed and distributed, and up to the present, made false misrepresentations, as previously set forth herein, to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that said pharmaceutical products, alone and in combination, were safe, fit and effective for human consumption. At all times herein mentioned, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of the aforementioned drug products and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the aforementioned products.

93. The Defendants made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by

sales representatives and other authorized agents of said Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject products.

94. The foregoing representations by the Defendants, and each of them, were in fact false, in that the aforementioned products were not same, fit and effective for human consumption, the use of said products is hazardous to health, and said products have a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff as delineated herein.

95. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of the subject products.

96. In reliance on the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use the use of the aforementioned products. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used the subject products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities who were in a position to know the true facts.

97. As a result of the foregoing negligent misrepresentations by the Defendants, and each of them, Plaintiff suffered injuries and damage as alleged herein.

WHEREFORE, Plaintiff requests judgment against Defendants, and each of them, as follows:

1. For past and future general damages, according to proof;

2. For past and future medical and incidental expenses, according to proof;

3. For past and future loss of earnings and/or earning capacity, according to proof;

4. For prejudgment interest on all damages as is allowed by the laws of the Commonwealth of Massachusetts;

5. For past and future mental and emotional distress, according to proof;

6. For past and future costs of suit incurred herein; and

7. For such other and further relief as the Court deems just and proper;

PLAINTIFF CLAIMS A TRIAL BY JURY

Dated: April 26, 2004

Respectfully submitted,

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